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Cerebral Bypass Surgery: Level of Evidence and Grade of Recommendation

Esposito, Giuseppe ; Sebök, Martina ; Amin-Hanjani, Sepideh ; Regli, Luca

Abstract: BACKGROUND AND AIMS Cerebral bypasses are categorized according to function (flow augmentation or flow preservation) and to characteristics: direct, indirect or combined bypass, extra-to-intracranial or intra-to-intracranial bypass, and high-, moderate- or low-capacity bypass. We critically summarize the current state of evidence and grades of recommendation for cerebral bypass surgery. METHODS The current indications for cerebral bypass are discussed depending on the function of the bypass (flow preservation or augmentation) and analyzed according to level of evidence criteria. RESULTS Flow-preservation bypass plays an important role in managing complex intracranial aneurysms (level of evidence 4; grade of recommendation C). Flow-preservation bypass is currently only very rarely indicated in the treatment of cerebral tumors involving major cerebral arteries (level of evidence 5; grade of recommendation D). The trend has evolved in favor of partial resection and radiotherapy. To preserve the flow, the bypass is always a direct bypass.Flow-augmentation bypass is currently recommended for Moyamoya patients with ischemic symptoms and compromised hemodynamics (level of evidence 4; grade of recommendation C) and patients with hemorrhagic onset (level of evidence 1B; grade of recommendation A). Flow-augmentation bypass is currently not recommended for patients with recently symptomatic carotid artery occlusion, even in the setting of compromised cerebral hemodynamics (level of evidence 1A; grade of recommendation A), but may be considered in patients with hemodynamic failure and recurrent medically refractory symptoms as a final resort (level of evidence 5; grade of recommendation D). CONCLUSIONS The results of recent randomized clinical trials narrow the indication for cerebral bypass in the setting of ischemic cerebrovascular disease. However, cerebral bypass is still very useful for managing complex intracranial aneurysms (not amenable to selective clipping or endovascular therapies) and is the only treatment option for managing symptomatic patients with Moyamoya vasculopathy and impaired brain hemodynamics.

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Cerebral bypass surgery: level of evidence and grade of recommendation.

Giuseppe Esposito[1], Martina Sebök[1], Sepideh Amin-Hanjani[2], Luca Regli[1]

[1]: Department of Neurosurgery, University Hospital Zurich, University of Zurich,

[2]: Department of Neurosurgery, University of Illinois at Chicago; Neuropsychiatric Institute, Rm 451N, 912 S Wood St, M/C 799, Chicago, IL 60612, USA

Corresponding author:

Giuseppe Esposito, MD, PhD
Department of Neurosurgery
University Hospital Zurich
Frauenklinikstrasse 10 - CH-8091 Zürich
Telefon: +41-44-2558656
TeleFax: +41-44-2554387
Email: giuseppe.esposito@usz.ch

Summary

Background and aims. Cerebral bypasses are categorized according to function (flow-augmentation vs flow-preservation), and to characteristics: direct vs indirect vs combined bypass, extra-to-intracranial vs intra-to-intracranial bypass, high- vs moderate- vs low-capacity bypass. We critically summarize the current state of evidence and grades of recommendation for cerebral bypass surgery.

Methods. The current indications for cerebral bypass are discussed depending on the function of the bypass (flow-preservation vs -augmentation) and analyzed according to level of evidence criteria.

Results. Flow-preservation bypass plays an important role for managing complex intracranial aneurysms (level of evidence 4; grade of recommendation C). Flow-preservation bypass is currently only very rarely indicated in the treatment of cerebral tumors involving major cerebral arteries (level of evidence 5 – grade of recommendation D): the trend has evolved in favor of partial resection and radiotherapy. To preserve the flow, the bypass is always a direct bypass.

Flow-augmentation bypass is currently recommended for Moyamoya patients with ischemic symptoms and compromised hemodynamics (level of evidence 4; grade of recommendation C) and Moyamoya patients with hemorrhagic onset (level of evidence 1B - grade of recommendation A). Flow-augmentation bypass is currently not recommended for patients with recently symptomatic carotid artery occlusion even in the setting of compromised cerebral hemodynamics (level of evidence 1A - grade of recommendation A), but may be considered for patients with hemodynamic failure and recurrent medically refractory symptoms as a final resort (level of evidence 5 – grade of recommendation D)

Conclusions: The results of recent RCTs narrow the indication for cerebral bypass in the setting of ischemic cerebrovascular disease. However cerebral bypass is still very useful for managing complex intracranial aneurysms (not amenable to selective clipping or endovascular therapies) and the only treating option for managing symptomatic patients with Moyamoya vasculopathy and impaired brain hemodynamics.

Keywords: cerebral bypass, cerebral revascularization, evidence-based medicine, grades of recommendation, indications, level of evidence.

Background

In the current neurosurgical practice different types of bypasses can be distinguished. According to their function, cerebral bypasses can be classified into “flow-augmentation” and “flow-preservation”.[8, 12]

The aim of a flow-augmentation bypass is to restore blood flow to a hypoperfused brain territory in order to avoid stroke in patients with symptomatic steno-occlusive diseases of major cerebral arteries.[12, 16]

The aim of a flow-preservation bypass is to replace blood flow to a brain territory previously perfused via a major vessel, the sacrifice of which is necessary to treat an underlying disease (such as an aneurysm). [12, 14, 38]

Bypass surgery is categorized into direct, indirect and combined procedures. A direct bypass consists of a direct microvascular anastomosis between a donor artery (for instance the superficial temporal artery – STA) and an intracranial recipient artery, and instantly delivers blood flow to the brain. [6, 12, 14, 16, 28] Depending on the choice of the donor artery, direct bypass is classified asextra-to-intracranial (EC-IC) vs. intra-to-intracranial (IC-IC). Furthermore, the donor and the recipient artery can be anastomosed with vs. without graft interposition, depending on the interposition or not of a vascular graft (arterial or venous).[12] The bypass is traditionally named according to the donor and the recipient vessels (i.e.: superficial temporal artery to middle cerebral artery - STA-MCA - bypass).[9, 12, 14] Direct bypass procedures can be further categorized according to the amount of flow (capacity) provided: low (<50 ml/min) vs. intermediate (50-100 ml/min) vs. high-capacity (>100ml/min).[12, 38] It is important to match the flow to demand i.e. the bypass must supply adequate flow for the needs of the vascular territory that is revascularized.

Indirect bypasses rely on the overlay of vascularized tissue (i.e.: muscle, dura, pericranium, omentum) onto the cerebral cortex. The aim is to promote neoangiogenesis over time and achieve delayed revascularization. [12, 15, 27, 28]

Combined bypass consists of the "combination" of direct and indirect bypass in the same surgical session.[12, 16]

To *preserve* flow, the bypass must be a direct bypass, and needs to be performed before permanent occlusion of the vessel. To *augment* flow, direct, indirect and combined techniques can be applied.

Herein we summarize the current state of evidence and discuss the grades of recommendation for cerebral bypass surgery, using the "Oxford Centre for Evidence-Based Medicine (OCEBM) Levels of Evidence" for grading levels of evidence and recommendations (http://www.cebm.net).

Flow-preservation bypass

Bypass surgery plays an important role in managing complex intracranial aneurysms not amenable to endovascular therapy or selective clip reconstruction. [14]Treatment of such lesions may in fact require vessel occlusion or "trapping", which involves sacrifice of the arery bearing the aneurysm and/or efferent arteries.[12, 14, 17] The goal of any aneurysm treatment is however both aneurysm exclusion and preservation of blood flow to the brain. Therefore, bypass is essential to replace the flow provided by the sacrificed artery.[14, 17] In flow-preservation bypass surgery, a key point is that the bypass has to match the flow of the sacrificed artery: intraoperative quantitative flow measurements allow confirmation of flow-matching. [3, 12, 14]

The type of bypass performed in this setting is always a direct bypass, in order to deliver the flow instantly to the involved territory. By varying the bypass construct (end-to-side vs end-to-end vs side-to-side anastomosis; single vs double bypass) the bypass can be customized to the intracranial angioanatomy. [11, 12, 14, 17, 26, 38] Complex aneurysms are rare lesions and their variety and heterogeneity do not lend themselves to RCTs. [12] The utility of bypass for managing complex intracranial aneurysms has been demonstrated primarily by case series (level of evidence 4, grade of recommendation C – see table 2). [7, 14, 26, 38]

Radical removal of cerebral tumors involving the proximal brain vasculature can be impossible without sacrificing a major artery and replacing it with a bypass.[5, 12] The risk-benefit ratio for complete tumor resection combined with a bypass versus partial resection has evolved towards partial resection and adjuvant therapy (radio- or chemotherapy).[5, 12, 21] Flow-preservation bypass for tumors has substantially declined in frequency during the last decades. Bypass surgery can be considered only in very selected cases, and has to be balanced against whether the benefit of radical resection plus arterial sacrifice and bypass outweighs the risks in terms of improving survival with good quality of life. Cerebral tumors involving the proximal brain vasculature (i.e.: skull base tumors) are also a rare disease: the variety and heterogeneity of these lesions preclude RCTs. Only few case series, and expert opinion, are available (level of evidence 5, grade of recommendation D – see table 2). [7, 12, 22, 41]

Flow-augmentation bypass

Bypass surgery is the only effective treatment for managing patients with symptomatic Moyamoya vasculopathy and impaired brain hemodynamics. Bypass surgery has been shown to decrease both ischemic and haemorrhagic stroke rates [12, 16, 27, 32].

Direct, indirect and combined bypass procedures are used for treating Moyamoya.[27, 37] There is no definitive consensus on which procedure is superior.[15, 27] Traditionally, direct or combined bypass is used in adults, while indirect or combined bypass are applied in children.[12, 27, 37] .

The most common direct bypass is the STA–MCA bypass.[12, 16, 37] Among the indirect techniques, the following can be considered: encephalo-myo-synangiosis (EMS) [12, 16], encephalo-duro-myo-synangiosis (EDMS) [16], encephalo-arterio-synangiosis (EAS)[24], encephalo-myo-arterio-synangiosis (EMAS)[31], encephalo-duro-arterio-myo-synangiosis (EDAMS)[25], encephalo-duro-arterio-synangiosis (EDAS)[40], encephalo-duro-periosteal-synangiosis (EDPS)[16] , multiple burr-holes[23], omental transplantation[42].

Combined bypass offers the advantages of direct and indirect methods. However, the procedures are somewhat more complex and time-consuming.[12, 16, 27]

There are no RCTs which have studied the value of bypass surgery for prevention of ischemic stroke and cognitive deterioration in Moyamoya patients. However, there are a number of observational studies which strongly indicate that bypass benefits these patients [27, 36, 39] compared to natural history; there is an unfavorable annual ischemic stroke rate in untreated patients (up to 13.3%)[19] and a high rate of disease progression with subsequent symptom occurrence in non surgically treated hemispheres[12, 29]. In light of existing data, an RCT to test bypass surgery efficacy for prevention of ischemic stroke recurrence and cognitive deterioration in symptomatic Moyamoya patients is unlikely be performed. [12, 27, 36, 39] due to a lack of equipoise. Based on existing observational studies, surgery is routinely recommended for children and adults with ischemic symptoms and compromised hemodynamics (level of evidence 4; grade of recommendation C – see table 2).[7, 12, 16, 27, 34, 36, 39]

As for hemorrhagic moyamoya disease, bypass surgery has RCT evidence demonstrating its efficacy in preventing recurrence of hemorrhagic stroke in patients with Moyamoya Diseases (MMD) ,[32]. Although statistically marginal, the Japanese Adult Moyamoya (JAM)Trial showed that direct (or combined) bypass surgery for adult patients with haemorrhagic-MMD reduces the re-bleeding rate and improves patient prognosis during the 5 years following enrolment (level of evidence 1B - grade of recommendation A) (See table 2).[7, 32] Bypass is thought to improve cerebral hemodynamics, and reduce the hemodynamic stress on the rupture-prone fragile Moyamoya collateral vessels.[32]

The topic of flow-augmentation bypass in patients with symptomatic cerebrovascular atherosclerotic occlusion of extracranial or intracranial major arterieshas been extensively debated in the past. [1, 13, 33] The main question has been:whether STA-MCA bypass (plus medical therapy) benefit patients with symptomatic cerebrovascular atherosclerotic occlusion in comparison to medical therapy.

To answer this question, RCTs have been conducted. The *"EC-IC Bypass Trial"* [1], the first prospective RCT in these field published in 1985, showed no significant advantage of bypass surgery in reducing the incidence of fatal and nonfatal ischemic strokes.[1, 35] This study was hotly debated: [4] among the various criticisms, the most important was related to the lack of hemodynamic criteria used to identify and select high-risk patients who might benefit from bypass.[12]

A Cochrane review[18], published in 2010, reported the results of 21 trials (two randomized and 19 non-randomized studies) for patients with symptomatic carotid occlusion. Bypass was shown to be neither superior nor inferior to medical care alone.[12, 18]

The "*Carotid Occlusion Surgery Study (COSS)"* [33] is a RCT whose results were published in 2011. In this study patients were selected based on very strict hemodynamic criteria, to identify those high-risk patients who might benefit most from bypass.[10, 20, 35]. However, STA-MCA bypass (plus medical therapy) was shown to provide no clinical benefit over medical therapy alone. [12, 33].

An ancillary study to COSS,, the *"Randomized Evaluation of Carotid Occlusion and Neurocognition" (RECON) Trial* [30] tested neurocognition at 2 years in COSS patients. . and was unable to identify a benefit of bypass when compared to medical therapy alone. [30].

Both the EC-IC Bypass Trial and COSShave generated level I evidence indicating no benefit of bypass forpatients with recently symptomatic carotid artery occlusion (in comparison to medical therapy alone).[1, 33, 35] Bypass failed to show benefit both because medical therapy performed better than in the past and because of the relatively high complication rate in the perioperative period, (most of which was non-bypass related) potentially due to the fragility of these flow-compromised patients. [12] Bypass is therefore currently not indicated for these patients (level of evidence 1A, grade of recommendation A) [7, 12, 30, 33].

However, there are subcategories of patients, not included in these RCTs (EC-IC Bypass trial and COSS), for whom flow-augmentation bypass could still be of benefit and may be used as a last resort to avoid disabling stroke despite optimal medical and interventional management: [2, 12] (1) patients presenting with ongoing hemodynamic symptoms (postural or with blood pressure variations); (2) patients having acute stroke with evidence of persistent oligemic brain tissue at risk of infarction (penumbra).

Currently, two other studies are underway. One, the *"Carotid and Middle Cerebral Artery Occlusion Surgery Study" (CMOSS)*, in China (ClinicalTrials.gov NCT01758614), and the other, the *"EDAS (Surgical) Revascularization in patients with Symptomatic Intracranial Arterial Stenosis*

(ERSIAS)", in the USA. Both may give new insights into the role of direct and indirect bypass respectively (ClinicalTrials.gov NCT01819597).

Conclusion

Cerebral bypass still represents an important treatment option for managing specific cerebrovascular conditions.

Flow-preservation bypass plays an important role for managing complex intracranial aneurysms (level of evidence 4; grade of recommendation C). Flow-preservation bypass is only very rarely indicated in the treatment of cerebral tumors involving major arteries (level of evidence 5 – grade of recommendation D), where the trend has evolved in favor of partial resection and radiotherapy. To preserve flow, the bypass is always a direct bypass.

Flow-augmentation bypass is currently recommended for Moyamoya patients with ischemic symptoms and compromised hemodynamics (level of evidence 4; grade of recommendation C) and patients with Moyamoya disease with hemorrhagic onset (level of evidence 1B - grade of recommendation A). Flow-augmentation bypass is currently not recommended for patients with recently symptomatic carotid artery occlusion failure of cerebral hemodynamics (level of evidence 1A - grade of recommendation A), but may be considered in select patients with refractory hemodynamic symptoms (level of evidence 5 – grade of recommendation D).

BYPASS TYPES			
Function of bypass	***Flow-augmentation***		
	Flow-preservation		
Type of	***Direct bypass***	EC-IC	No graft interposition

revascularization		bypass	Graft interposition
		IC-IC bypass	No graft interposition
			Graft Interposition
	Indirect bypass	EMS	
		EDMS	
		EAS	
		EMAS	
		EDAMS	
		EDAS	
		EDPS	
		Multiple burr-holes	
		Omental transplantation	
	Combined bypass	Direct + indirect bypass procedures	
Characteristics of the anastomosis	***Type***	Occlusive (conventional)	
		Non-Occlusive (ELANA)	
	Anatomy	End-to-side	
		End-to-end	
		Side-to-side	
Capacity	***Low*** (<50 ml/min)		
	Intermediate (50-100 ml/min)		
	High (>100 ml/min)		

Table 1: Bypass types. EAS: encephalo-arterio-synangiosis. EC-IC: extra-to-intracranial. EDAMS: encephalo-duro-arterio-myo-synangiosis. EDAS: encephalo-duro-arterio-synangiosis. EDMS: encephalo-duro-myo-synangiosis. EDPS: encephalo-duro-periosteal-synangiosis. ELANA: Excimer Laser Assisted Non-occlusive Anastomosis. EMAS: encephalo-myo-arterio-synangiosis. EMS: encephalo-myo-synangiosis. IC-IC: intra-to-intracranial.

Bypass role	Indication	Bypass Indicated	Level of evidence	Grade of recommendation	RCT
FLOW-PRESERVATION	Complex Aneurysms*	Yes	4	C	N.A.

	Tumors	Rarely	5	D	N.A.
FLOW AUGMENTATION	Moya ischemic	Yes	4	C	/
	Moya hemorrhagic	Yes	1B	A	Yes
	Symptomatic cerebrovascular atherosclerotic steno-occlusive disease	No**	1A	A	Yes

Table 2: Current indications for cerebral bypass: level of evidence (N.A.: not applicable). The "Oxford Centre for Evidence-Based Medicine (OCEBM) Levels of Evidence" has been used for grading levels of evidence and recommendations (http://www.cebm.net).

* Complex aneurysms not amenable to direct clipping or definitive endovascular therapy

** may be indicated in select cases presenting with ongoing hemodynamic symptoms (postural or with blood pressure variations) despite maximal medical management or patients having acute stroke with evidence of persistent oligemic brain tissue at risk of infarction (penumbra).

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